DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 13, 2014

Merit Medical Systems, Inc.
Siobhan King
RA Specialist II
Parkmore Business Park West
Galway, Ireland

Re: K142265
Trade/Device Name: One Snare Endovascular Microsnare System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: August 12, 2014
Received: August 15, 2014

Dear Ms. Siobhan King,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142265

Device Name
ONE Snare Endovascular Microsnare System

Indications for Use *(Describe)*
The ONE Snare Endovascular Microsnare System is intended for use in adult and pediatric populations for the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extra-cranial anatomy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 +353 91-703761 +353 91-703772 Mark Mullaney 11-Nov-14 1721504
	Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Ireland Ltd. Parkmore Business Park, Galway, Ireland +353 91-703752 +353 91-703772 Siobhan King 11-Nov-14 9616662
Subject Device	Trade Name: Common/Usual Name: Classification Name:	ONE Snare Endovascular Microsnare System Percutaneous Retrieval Device Device, Percutaneous Retrieval
Predicate Device	**Primary Predicate Device# 1:** Trade Name: Classification Name: Premarket Notification: Manufacturer: **Reference Device# 2:** Trade Name: Classification Name: Premarket Notification: Manufacturer:	 Amplantz “GOOSE NECK” Microsnare Catheter, Percutaneous K970668 ev3 (Microvena Corp.) Merit ONE Snare System Percutaneous retrieval device K122088 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.5150 FDA Product Code: MMX Division of Cardiovascular Devices	
Intended Use	The ONE Snare Endovascular Microsnare System is intended for use in adult and pediatric populations for the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extra-cranial anatomy.	

Device Description	ONE Snare Endovascular Microsnare System contains: (1) Snare, (1) Snare Catheter, (1) Insertion Tool and (1) Torque Device. The snare is constructed of nitinol cable and a gold plated tungsten loop. The pre-formed snare loop can be introduced through catheters without risk of snare deformation because of the snare's super-elastic construction. The snare catheter is constructed of polyether block amide (Pebax®) and contains a platinum/iridium radiopaque marker band.
Technological Characteristics	Technological characteristics of the subject Merit ONE Snare Endovascular Microsnare System are substantially equivalent to those of the Primary Predicate#1, the currently marketed Amplantz "GOOSE NECK" Microsnare, manufactured by ev3 Inc., 510(k) K970668 and Reference Device#2, Merit Medical ONE Snare System, 510(k) K122088 for the following performance data – Corrosion Testing, Luer Testing and Packaging Testing.
Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests performed on the Merit ONE Snare Endovascular Microsnare System were designed to demonstrate that the device meets critical design specifications as well as clinical performance attributes for its intended use. Where appropriate, the tests were based on the requirements of the following documents: • FDA guidance Coronary and Cerebrovascular Guide Wire Guidance January 1995. • ISO 11070:1998, *Sterile Single-Use Intravascular Catheter Introducers* • ISO 10555-1 2013 *Intravascular catheters – Sterile and single use catheters - Part 1: General Requirements.* • ISO 594-1:1986*, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements* • ISO 594-2:1998, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings* • ASTM F 2096-11 *Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)* • ASTM F 1929-12 *Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration* • ASTM F88/F88M-09 *Standard Test Method for Seal Strength of Flexible Barrier Materials* • ASTM D4169–09 *Standard Practice for Performance Testing of Shipping Containers and Systems* • ASTM F1980-07 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* • ISO 2233:2000 *Packaging – Complete, filled transport packages and unit loads – conditioning for testing* • ISO 11135:2014 – *Sterilization of health care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices* • ISO 10993-1: 2009, *Biological Evaluation of medical Devices Part 1: Evaluation and Testing within a risk management process,* and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.

Safety & Performance Tests (continued)

The Merit ONE Snare Endovascular Microsnare System was compared to the predicate devices for various performance attributes that demonstrate the substantial equivalence of the device. The following is a list of all significant testing that was successfully completed:

Catheter & Insertion Tool

- Surface Finish
- Radiopacity
- Catheter tip atraumatic
- Marker band placement
- Effective Length
- ID & OD
- Catheter stiffness
- Markerband retention
- Tip integrity
- Torque Strength
- Kink resistance
- Buckling force
- Freedom from Liquid leakage
- Freedom form Air leakage
- Peak tensile force of catheter at hub
- Force at break – insertion tool at hub
- Hub with Female luer testing
- Corrosion Resistance

ONE Snare Endovascular Microsnare System

- Snare Loop Resistance
- Guide Catheter resistance
- Snare shape integrity
- Insertion Tool Fitment
- Snare insertion
- Insertion Tool tear away force
- Snare jacket after insertion tool removal inspection
- Snare loop protruding

Snare

- Size designation
- Snare Head Assembly
- Radio detectability
- Surface Finish
- Tensile strength
- Torqueability
- Torque Strength
- Flexing Test
- Fracture Test
- Tip Flexibility
- Corrosion Resistance

Biocompatibility testing included

- Cytotoxicity
- Sensitization
- Irritation

Safety & Performance Tests (continued)	• Acute Systemic Toxicity • Pyrogenicity • Genotoxicity • Hemolysis • Thrombogenicity • Complement Activation • Chemical Tests Packaging performance before and after exposure to accelerated aging and simulated shipping and handling conditions • bubble emission • dye penetration • seal peel tensile strength • burst strength • visual inspection
Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject Merit ONE Snare Endovascular Microsnare System is substantially equivalent to the Primary Predicate#1 Amplantz "GOOSE NECK" Microsnare, K970668, manufactured by ev3 Inc and the Reference Device#2 Merit Medical ONE Snare System, K122088 for Performance data.